

REMARKS

The Office Action of April 21, 2003 has been received and considered. In the Office Action, an objection was made to the specification. Also, claims 1-20 were rejected under 35 U.S.C. §103(a).

Claims 3, 4, 16, 21 and 22 have been cancelled. Claims 1, 5, 6, 8, 9, 12, 24, 15, 19 and 20 have been amended. Claims 1, 2, 5-15 and 17-20 remain pending. Reconsideration of the application is requested.

The drawings were objected to in the Office Action for reasons set forth on the PTO-948 accompanying the outstanding Office Action. Also, it was suggested that Figure 2 be cancelled. A formal copy of Figure 1 is being filed concurrently herewith. This formal figure overcomes the objections of the draftsman. Approval of Figure 1 is requested. In view of the cancellation of claims 21 and 22, Figure 2 has been cancelled. Withdrawal of the objections to the figures is requested.

An objection was made to the specification because of the presence of an embedded hyperlink. The specification has been amended to remove the embedded hyperlink. Withdrawal of the objection is requested.

An aspect of the present invention includes identifying patients at risk for developing breast precancer or cancer. The method comprises the steps of introducing a ductal access tool including at least one elongated lumen into a breast duct and introducing a fluid into the breast duct through the elongated lumen. The method also comprises the steps of retrieving a ductal fluid sample from within the breast duct through the same lumen that was used to introduce the fluid into the breast duct, and detecting a viral agent in the retrieved ductal fluid sample. In this embodiment, the ductal fluid sample collected through the lumen is free of any ductal fluid from

another duct of the breast. The viral agent can be selected from the group consisting of a whole virus, a portion of a virus, a viral protein, a viral nucleic acid, and a viral marker, in the sample.

An additional object of the invention is to treat a patient having a viral infection that places the patient at risk for developing breast precancer or cancer. This aspect of the invention includes a method of treating a patient at risk for, or having, breast precancer or breast cancer. The method comprises the steps of introducing a ductal access tool having at least one elongated lumen into a breast duct, introducing a fluid into the breast duct through the elongated lumen and retrieving a ductal fluid sample from within the breast duct through the same lumen that was used to introduce the fluid into the breast duct. The method also comprises the steps of detecting a viral agent in the retrieved ductal fluid sample from the breast duct, and delivering to the patient a composition comprising an antiviral agent specific for the detected viral agent. The antiviral agent can be delivered intraductally to any duct in which the viral agent is detected.

Claims 1-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,221,622 to Love et al. in view of U.S. Patent No. 5,763,415 to Sukumar et al., Makita et al. (Breast Cancer Research, 1991), King et al. (JNCL, 1983), Noguchi et al. (American Journal of Pathology, 1994), Gross (Intervirology, 1997) and Androphy (Ciba Found. Symposium, 1986).

The patent to Love discloses a method of obtaining cellular material from within a breast duct using a multiple lumen tool. In the Love method, a multiple lumen tool including a first, infusion lumen and a second, collection lumen is introduced into a breast duct. In operation, the tool introduces a saline fluid into the breast duct through the first, infusion lumen. After the saline fluid is introduced into the breast duct, a ductal fluid sample is collected from within the breast duct through the second, collection lumen. As a result, the patent to Love discloses the

use of different lumens for introducing fluid into a duct and collecting a fluid sample from within a duct. As a result, the patent to Love does not disclose the method set forth in the pending claims.

The patent to Sukumar does not cure the deficiencies of the patent to Love. The Office Action relies on Sukumar to teach the introduction of a treatment agent into a breast duct. Sukumar teaches the introduction of epithelial destroying agents in a breast duct in order to destroy cells of the ductal epithelium. However, to the extent that Sukumar does disclose the administration of pharmaceutical compositions, it does not teach or suggest the recited steps of introducing a tool into a breast duct, introducing a fluid into the duct through a lumen and retrieving a ductal fluid sample from within the duct through the same lumen. Therefore, Sukumar would not have motivated one of ordinary skill in the art to modify the disclosure of the patent to Love to arrive at the recited methods because the combination of Love and Sukumar would not arrive at the methods recited in claims 1 and 12.

The publication to Makita discloses a method of performing biopsies on patients that experience nipple discharge. This publication is relied upon to disclose that it was known at the time of the present invention that papilloma can be present in the epithelial cells of the breast. The publication to King discloses obtaining ductal fluid by nipple aspiration and analyzing the fluid to determine if atypical proliferative disease (APD) is present in the nipple aspirate fluid. As is known, nipple aspiration does not include the introduction of an elongated lumen into a breast duct. The publication to King is relied upon to teach that papilloma virus can be detected in a fluid obtained from a breast duct. However, the publications to Makita and King do not disclose the steps of (1) introducing a fluid into a duct through a lumen of a ductal access tool and (2) retrieving a sample from within the duct through the same lumen of the same tool.

Therefore, it would not have been obvious to one of ordinary skill in the art to modify the combination of Love and Sukumar with the methods disclosed in the publications to Makita and King for the resulting combination would not arrive at the methods recited in claims 1 and 12.

Similarly, the publications to Noguchi, Androphy and Gross G fail to disclose the steps recited in claims 1 and 12. For example, while these publications may disclose the techniques for detecting and treating papilloma virus, none of these publications discloses a method that includes the steps of (1) introducing a fluid into a duct through a lumen of a ductal access tool and (2) retrieving a sample from within the duct through the same lumen of the same tool. Therefore, it would not have been obvious to modify the method of Love with the disclosures of Noguchi, Androphy and Gross G for the resulting combination would not arrive at the recited methods.

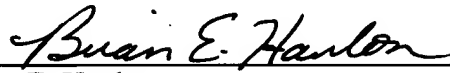
For all of the above-discussed reasons, it is submitted that the combination of references set forth in the outstanding Office Action would not have been obvious to the ordinary artisan. Therefore, withdrawal of the outstanding rejections is requested.

The application is in condition for allowance. Notice of such is respectfully requested. Should the Examiner find any issues outstanding, the Examiner is invited to contact the undersigned.

It is believed that no fee is required for this submission. If any fees are required, the Commissioner is authorized to debit our Deposit Account No. 19-0733, accordingly.

Respectfully submitted,

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Dated: *7/21/03*